K094007

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR - 8 2010

Submitter

Company:.....3M ESPE AG

Street:.....ESPE Platz

ZIP-Code, City:.....D-82229 Seefeld

Federal State: .....Bavaria

Country: .....Germany

Establishment Registration Number .....9611385

Official Correspondent: .....Dr. Desi W. Soegiarto,

.....Regulatory Affairs Specialist

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Date:.....March 11, 2010

Name of Device

Proprietary Name:.....Unicem Aplicap/Maxicap

Classification Name:.....Dental cement other than zinc oxide-eugenol

Common Name: .....Self adhesive cement

Predicate Devices

Panavia F 2.0 by Kuraray Medical Inc., Japan .....K032455

Maxcem 2 by Kerr Corporation, U.S.A.....(K073209) (presumably marketed as Maxcem Elite)

Description for the Premarket Notification

Unicem Aplicap/Maxicap is classified as a Dental cement other than zinc oxide-eugenol (21 C.F.R. § 872.3275 [b]) because it is a device composed of various materials other than zinc oxide-eugenol.

Unicem Aplicap/Maxicap cements are dual-curing, self-adhesive resin cements available in two single dose delivery systems in capsules (K020256). They are used for the permanent cementation of indirect restorations made of ceramic, composite, or metal, and for posts and screws. Bonding and conditioning of the prepared tooth structure are not necessary with Unicem Aplicap™ and Maxicap™.

Unicem Aplicap™ and Unicem Maxicap™ release fluoride ions, and are available in various shades. Unicem Aplicap™ and Unicem Maxicap™ contain bifunctional (meth)acrylate.

Unicem Aplicap™ and Unicem Maxicap™ have been cleared under K020256. This 510(k) Premarket Notification has been submitted in order to seek for clearance for new Indications for Use:

Final cementation of 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis)

Final cementation of ceramic, composite or metal restorations on implant abutments & Cementation of abutments made of Lava™ zirconium oxide ceramic

Predicate devices to which Unicem Aplicap™ and Maxicap™ have been compared are Panavia F 2.0 by Kuraray Medical Inc., Japan (K032455) and Maxcem Elite by Kerr Corporation, U.S.A (K073209). Like its predicate devices Unicem Aplicap™ and Maxicap™ are dual-curing resin based cement system containing methacrylate. Like Panavia F 2.0, Unicem Aplicap™ and Maxicap™ release Fluoride.

The comparison for performance data and indications for use shows that Unicem Aplicap™ /Maxicap™ is substantially equivalent to its predicate devices Panavia F 2.0 by Kuraray Medical Inc., Japan (K032455) and Maxcem Elite by Kerr Corporation, U.S.A (K073209).

To provide evidence for safety biocompatibility testing was carried out. The results show that Unicem Aplicap™ / Maxicap™ is a safe device.

In summary, it can be concluded that safety and effectiveness requirements for Unicem are completely met.

Indications for Use:

Final cementation of ceramic, composite or metal inlays, onlays, crowns, bridges, 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis)

Final cementation of post and screws

Final cementation of ceramic, composite or metal restorations on implant abutments

Cementation of abutments made of Lava™ zirconium oxide ceramic

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Desi W. Soegiarto
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GERMANY

APR - 8 2010

Re: K094007
Trade/Device Name: Unicem Aplicap/Maxicap
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Codes: EMA
Dated: March 23, 2010
Received: March 25, 2010

Dear Dr. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.\

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K094007

# Indications for Use

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|---|---|
| 510(k) Number (if known): | K094007 |
| Device Name: | Unicem Aplicap/Maxicap |
| Indications For Use: | Final cementation of ceramic, composite or metal inlays, onlays, crowns, bridges, 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis)<br>Final cementation of post and screws<br>Final cementation of ceramic, composite or metal restorations on implant abutments<br>Cementation of abutments made of Lava™ zirconium oxide ceramic |

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

B.S. Beck DDS for Dr. K. P. Mulay

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



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